

# ER/DL SPL Team Meeting

## Minutes

### March 3, 2010

Chair of today's meeting: Pat Cowall-Hanover

#### Topics discussed

1. Update from DIA – discussion on providing link to the SPL file submitted to the ELIST system for approved implemented labeling.
  - a. FDA is working on a new approval letter that will specify that sponsors should submit to drug listing and provide link in submission to review division.
  - b. Pat is working with their eCTD group to figure out issues and options.
  - c. Purdue has used the link. They have included the link in their cover letter. Be careful to format the link correctly: GUID/GUID.xml
  - d. Pat will potentially ask Lonnie to invite Virginia Ventura (or someone from their eCTD group) to come to one of the process team meetings to give us her suggestions for managing the link.
2. Update from Process team: Pharmacologic class list posted to SPL Resources site:
  - a. Questions should be sent to SEALD Team,
  - b. Per Terry Brunone, [If you have questions about the FDA established pharmacologic class indexing, or want to bring the FDA's attention to an error in the table, please address to: SEALD@fda.hhs.gov.](#)
3. Indexing:
  - a. Randy Levin has requested input on how to best approach the next phase of indexing: They plan to work on indication, and they would appreciate comments on what would be most valuable.
  - b. SPL Lead team is coordinating an effort to develop comments – in particular working not only with sponsors, but also data providers / end- users of the information (ie First Data Bank).
4. Questions/Updates:
  - a. Michelle Halliez: When will the validator be turned on to validate establishments - hopefully not soon!
    - i. Frustrations from 3<sup>rd</sup> parties – and that everything needed to match.
    - ii. We are worried about nomenclature (legal ownership), addresses, ownership,
    - iii. How precise do we need to be? In the past, it didn't need to be precise.
    - iv. Business operations terms are changing.
      1. Pat took the assignment to follow-up with Lonnie on the need for the business operations to match between the DL and ER. Lonnie's response is that the business operations DO need to match between the ER and DL SPLs.
      2. Sponsors will need to follow up with their manufacturers, so that they are using consistent terms.

3. Layla has stated that the business operations will not be defined by their group, but referenced the regulations. Pat to F/U: Where are these terms defined in the regulations.
  - b. Michelle Halliez: Do we have documentation saying FDA wants us to file establishments under the legal entity name associated with the site, not necessarily the registrant which can be different. Does anyone have written documentation on what this means?
    - i. Ownership changes, acquisition. The site may stay the same, but the owner may be changing. Ie "What is the name of the establishment."
    - ii. The name should match what is known to D&B.
    - iii. If the legal ownership changes, does the DUNS number change? No. The DUNS numbers stays the same! (per Jean at Hospira and Pat at Lilly)
  - c. Howard: Effective time of the registration must match the date in the SPL. Ie the effective time in the SPL must match the year of submission- new validation rule.
5. Outstanding assignments:
  - a. Pat to follow-up with DRLS as to where to find definitions of business operation terms in the SPL.